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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,253	STOUT, ROBERT L.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4 and 7-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4 and 7-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received October 5, 2005. Claims 3, 4 and 7-31 are pending and under examination.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 and 7-31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in its recitation of first and second fluid samples. The claim recites "said second fluid sample comprising said first fluid sample and HCV antigen from said HCV antibody assay . . . ." This language is indefinite because it is unclear whether there is in fact a second fluid sample since the second and first fluid samples are the same; both samples comprise fluid from the first sample and HCV antigen from the antibody assay. The following language is

recommended: "measuring the optical density of a second fluid sample, said second fluid sample comprising (i) a portion of the first fluid sample prior to conducting the HCV antibody assay, and (ii) antigen from said HCV antibody assay."

Claim 12 is also indefinite in the recitation of "the individual providing the first fluid sample . . . ." This language is indefinite because it is unclear whether the method involves fluid samples from a first and a second individual. That is, since the second sample "comprises" said first fluid sample, it could be a mixture of samples from a first and a second individual. The following language is suggested: "predicting that the individual providing said samples . . . ."

Claim 19 is indefinite in the recitation of "chronic HCV." This language does not clearly indicate the nature of the HCV strain since different HCV types and subtypes may become a chronic infection. The following language is suggested: "predicting that an individual . . . is chronically infected with HCV . . . ."

Claim 19 is also indefinite in that it is unclear whether "said correlation" refers to the comparing step (i.e. "comparing said determined optical density"), or the "standard optical density values correlated with probabilities of chronic HCV infection . . . ." The following language is suggested: "predicting whether or not the individual has chronic HCV based on said comparison."

Claim 26 is indefinite in the recitation of "using said measured optical density as a test for chronic HCV infection." This language is indefinite because one skilled in the art would not understand the scope of the method. That is, the skilled artisan would not be able to appreciate the steps involved in "using . . . optical density as a test for chronic HCV infection."

Claim 31 is indefinite in the recitation of "an antibody-based assay" since it is unclear whether the assay is detecting HCV antibody or HCV antigen. If Applicants intended to the antibody-based assay to refer to an assay for detecting antibodies, the following language may be used to overcome this rejection: "contacting said fluid sample with an HCV antigen and detecting an interaction the antigen and antibody from the sample . . . ."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4 and 7-31 are rejected under 35 U.S.C. 102(b) as being anticipate by Scheffel (WO 00/26673).

Applicants claim a method for detecting chronic HCV infection in an individual comprising contacting a fluid sample from the individual with an HCV antigen, measuring the optical density of said fluid sample, comparing said optical density with at least one optical density value from at least one chronically infected individual, and determining that the individual is chronically infected with HCV if the comparison reveals that the optical density of the sample is similar to the at least one optical density value from the at least one chronically infected individual.

Scheffel discloses a method for determining chronic HCV infection comprising contacting a test sample suspected of containing HCV antibody with antigen specific for said

antibody, detecting an amount of antibody present in the sample, and correlating high antibody titer (as compared to at least on previous test result) with a diagnosis of chronic HCV infection (p. 6, lines 16-27). Scheffel further teaches measuring HCV antibody concentration using optical density (p. 13, lines 13-15). Scheffel also discloses making the correlation of high antibody titer between the individual providing the sample and (i) individuals that have cleared the infection, and (ii) individuals that remain chronically infected (p. 12, lines 13-28). Based on this disclosure, Scheffel anticipates the subject matter of claims 3, 4 and 7-31.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 4 and 7-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheffel et al. ("Scheffle").

Applicants' invention is drawn to a method of detecting chronic hepatitis C virus (HCV) comprising:

obtaining a sample from an individual;

performing an HCV immunoassay on said sample;

determining the optical density of said sample;

comparing the optical density of the sample with a set of optical density values that are obtained from samples taken from (a) individuals known to have chronic HCV, and (b) individuals who have cleared the HCV infection but remain positive for HCV antibody;

and determining the individual has chronic a HCV infection based on the comparison of the sample with the set of optical density values.

Scheffel teaches many features of the claimed invention including performing an immunoassay on a sample from an individual suspected of having chronic HCV infection (page 8, lines 13-17), determining an optical density of the sample after performing the immunoassay (page 13, lines 6-15), and determining that the individual has chronic HCV based on a comparison of the level of antibody in the sample (as determined by optical density), with a predetermined level of antibody.

Assuming Scheffel does not expressly disclose detecting chronic HCV infection based on optical densities, including such a step would have been an obvious change. This is because Scheffel teaches using optical density as a measure of antibody concentration and it is well within the knowledge generally available to the skilled artisan to substitute one variable (i.e. optical density) for another (i.e. antibody concentration) when the variables are directly correlated. Thus, one skilled in this art would have been motivated to modify Scheffel to compare optical density values - instead of antibody concentration levels - in order to reduce the number of method steps. Moreover, one skilled in the art would have had a reasonable expectation of success using such a strategy since Scheffel teaches that optical density may be used to derive antibody concentration which is the variable that defines chronic HCV infection. Therefore, it would have been obvious to one of ordinary skill to modify Scheffel to detect chronic HCV infection based on a comparison of optical densities.

Assuming Scheffel does not expressly disclose detecting chronic HCV based on a comparison of optical density with a correlation curve, it would have been obvious to

incorporate this modification. Scheffel expressly suggests this step by teaching that chronic HCV can be predicted based on "a single point determination" if an antibody concentration (i.e. optical density) value is compared with values from a number of known chronic and self-limiting case (p. 12, lines 13-17). One skilled in the art could reasonably expect such a method to succeed since Scheffel teaches that elevated antibody levels, relative to a standard, can provide a prediction of chronic HCV infection.

Claims 13-18 and 20-25 recite a number of probability ranges, such as "said certain probability that the individual has chronic HCV infection being less than about 10% . . ." (e.g. claim 15). This limitation reads on Scheffel's providing a prediction that, based on antibody titer, the individual does not have chronic HCV. This is because by providing a prediction that the individual does not have chronic HCV, Scheffel provides a prediction that the probability of chronic HCV infection zero (i.e. less than 10%).

Response to Arguments

Applicants argue the rejection of the claims as obvious over Scheffel cannot be maintained because there is nothing in Scheffel to suggest using optical density as a predictor for chronic HCV infection. This argument is not persuasive because it ignores the other sources of motivation for combining references under 35 U.S.C. section 103. "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Here, the knowledge of persons of ordinary skill in the art would readily appreciate that antibody concentration may be

measured as a function of optical density. At the time of Applicants' invention, using optical density as a measure of antibody/antigen interaction was a routine method of experimentation. Thus, it would have been obvious to one of ordinary skill in the art to modify Scheffel to detect antibody concentration using a routine optical density assay.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 12/26/05

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